OPTICAL CUVETTE WITH PLATFORM-AND-WELL CONSTRUCTION

FIELD OF THE INVENTION

The present invention relates generally to electro-chemical analysis and more specifically to an optical format for fluid analysis.

BACKGROUND OF THE INVENTION

Optical testing of samples has become increasingly popular in recent years due to the speed, accuracy, and efficiency with which test results can be acquired through optical testing. Because of these benefits, optical testing is commonly used in medical applications such as glucose testing, with the sample fluid being blood. Generally, optical testing in medical applications involves allowing light to interact with a sample. In some applications, the sample may be combined with a reagent for testing. Optical testing may be accomplished using "formats," which allow for the collection of a sample, combination of the sample with a reagent, and optical testing of the sample.

Several problems arise in optical testing applications. A common problem with sample testing is the necessary sample size to allow reaction with a reagent and enable accurate testing. Many optical formats require sample sizes of 300 nl or greater. Further, optical formats often result in performance errors due to poor mechanical tolerances of the formats. When a reagent is used with an optical format, the reagent may be inconsistently placed within the format. For example, an improper amount of reagent or reagent placed in the wrong location may affect test accuracy. Formats resulting in improper control of sample volume—for example, deposition of an insufficient sample volume within a test area—decrease the accuracy of many prior art optical testing systems. Further, the costs of manufacturing optical formats can be high, and resulting formats are often larger than desired.

In order to increase the efficiency and accuracy of optical sample testing, it is desirable to provide an improved optical format.

SUMMARY OF THE INVENTION

According to one embodiment of the present invention, an optical format allows a very small sample volume to result in accurate optical testing.

According to some embodiments of the present invention, an optical format is

provided which allows accurate optical testing of sample volumes of approximately 50 nl.

According to some embodiments of the present invention, an optical format consists of two pieces designed to join into a single format allowing accurate testing of small optical volumes.

According to some embodiments of the present invention, optical formats allow the consistent placing of reagent within the optical format.

According to some embodiments of the present invention, reagent placement is facilitated by the use of a mesa upon which a reagent is placed during manufacturing of the format.

According to some embodiments of the present invention, sample volume is metered to a required amount within an optical format before the sample is allowed to react with a reagent within the optical format.

According to some embodiments of the present invention, an optical format is manufactured using continuous web processing to enable high-speed production of optical formats at low cost.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an optical format according to one embodiment of the present invention;

FIG. 2 is an exploded perspective view of an optical format according to one embodiment of the present invention;

FIG. 3 is a top cross-sectional view along the line 3-3 of the optical format of FIG. 1; and

FIG. 4 is a side cross-sectional view along the line 4-4 of the optical format of FIG. 1.

While the invention is susceptible to various modifications and alternative forms, specific embodiments are shown by way of example in the drawings and will be described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

FIG. 1 shows an optical format 10 according to one embodiment of the present invention. The optical format 10 may be used in the collection and optical testing of samples, for example in medical testing applications such as glucose testing or testing of other analytes in biological fluid analysis. The optical format 10 may be created using a variety of fabrication techniques, such as micro-molding, coining, or UV replication processes, and may be constructed of such materials as polycarbonate, polystyrene, and polyester. Formats according to the present invention may be individually cut out of sheet material, cut into one- or two-dimensional arrays, or cut into a circular disc arrangement. Continuous web processing may be used to manufacture formats and format members according to the present invention, resulting in lower processing costs.

The optical format 10 comprises a first format member 12 and a second format member 14. Though the first and second format members 12 and 14 are discussed in relation to top and bottom directions as shown in FIG. 1, it is to be understood that these labels are for the purposes of discussion and that the features of optical formats according to the present invention may be alternatively oriented in space—for example, features discussed in combination with the first format member 12 may be placed on a lower format portion according to some embodiments of the present invention.

The second format member 14 shown in FIG. 1 is provided with a sample fill nose 16. The sample fill nose 16 provides for the collection of sample fluid from a sample collection opening 18 and transport of the sample fluid from the sample collection opening 18 to a well 20. The well 20 is connected to a vent 22 provided with a vent opening 24. In the embodiment shown in FIG. 1, the sample collection opening 18 is provided on a front face 26 of the optical format, and the vent opening 24 is provided on a back face 28 of the optical format. According to some embodiments of the present invention, sample collection openings and vent openings may be provided on other faces of optical formats, or at face interfaces of optical formats, as required by particular applications of the optical format.

According to some embodiments of the present invention, the sample fill nose 16 transports sample fluid from the sample collection opening 18 to the well 20 via capillary action. The sample fill nose 16 is preferably provided with dimensions such that the open volume of the sample fill nose 16 is approximately equal to the volume of sample

fluid required for analysis within the well 20.

In an embodiment in which the sample fill nose 16 has a rectangular cross-section, the sample fill nose 16 has a height, h_n, a width, w_n, and a length, l_n. According to one embodiment of the present invention, the volume of sample preferred for testing within the well 20 is approximately 50 nl. In this embodiment, a sample fill nose 16 having a height h_n of approximately 100 μm, a width w_n of approximately 200 μm and a length, l_n, of approximately 2.4 mm is appropriate to fill the well 20 with the desired amount of sample fluid. Thus, the sample volume is appropriately metered by the sample fill nose 16 during sample collection. According to some embodiments of the present invention, it may be desirable to conduct testing with greater or lesser amounts of fluid, and the well 20 and the sample fill nose 16 may be sized to enable optimum fluid transport to the well 20. The dimensions of the format are dependent on the manufacturing process, but in general the maximum preferred sample volume of 1 μl limits the size of the format.

According to some embodiments of the present invention, a platform 28 is provided on an optical format member. The platform 28 is raised from an inner surface 30 of one of the optical platform members, as shown in FIG. 2. FIGS. 1 and 2 show the platform 28 extending downwardly from the inner surface 30 of the first platform member 12, but it is to be understood that optical formats according to the present invention may employ platforms extending upwardly from a bottom platform member. In the embodiment shown in FIGS. 1 and 2, the platform 28 extends downwardly from the inner surface 30 of the first optical format member 12 and into the well 20 provided in the inner surface 32 of the second optical format member 14.

The platform 28 extends a height h_p from the inner surface 30 of the first format member 12. The platform 28 may be a circular platform with a diameter d_p. According to one embodiment of the present invention, the height h_p of the platform 28 is approximately 50 μm and the diameter d_p of the platform 28 is approximately 1000 μm, but greater or lesser heights and diameters may be used in specific applications of the present invention. For example, heights ranging from about 25 μm to about 250 μm and diameters ranging from about 500 μm to about 2000 μm are preferred in some embodiments of the present invention.

For the platform 28 to enter the well 20, the well 20 is provided with a diameter,

d_w larger than the diameter d_p of the platform 28. According to one embodiment of the present invention, the diameter d_w of the well is approximately 1050 μm. Larger or smaller well diameters are possible. For example, well diameters ranging from about 550 μm to about 2050 μm are preferred in some embodiments of the present invention. Further, the well is provided with a depth h_w that is deeper than the height h_p of the platform 28, thereby forming a sample testing region 34, most easily seen in FIG. 4. According to one embodiment of the present invention, the sample testing region 34 has a height h_t of approximately 50 μm. Larger or smaller testing region heights are possible. For example, testing region heights ranging from about 25 μm to about 100 μm are preferred in some embodiments of the present invention.

The vent 22 extends from the sample testing region 34 toward the rear face 36 of the optical format 10. According to some embodiments of the present invention, the vent 22 serves to ensure capillary movement of sample from the sample collection opening 18 toward the sample testing region 34. The vent 22 of the embodiment shown in FIGS. 1-4 has a rectangular cross-section with a height h_v, a width w_v and a length l_v. According to one embodiment of the present invention, the height h_v of the vent is approximately 100 μm, the width w_v of the vent is approximately 500 μm, and the length l_v of the vent is approximately 400 μm. Other vent dimensions are contemplated in other embodiments of the present invention. For example, vent heights ranging from about 50 μm to about 200 μm, vent widths ranging from about 50 μm to about 200 μm, and vent lengths ranging from about 50 μm to about 500 μm are preferred in some embodiments of the present invention. In addition to increasing capillary force in the capillary gap of the sample testing region 34, the vent 22 may provide an area for sample overfill.

The platform 28 may be provided with a reagent thereon designed to react with the sample in the sample testing region 34. Reagent may be placed on the platform via pump depositing, or by methods such as printing, pin deposition, or ink jetting. A reagent may be retained on the platform 28 by oven-drying before assembly of the optical format 10. According to one embodiment of the present invention, a reagent is deposited on the platform 28 before the optical format members are joined together. In this embodiment of the invention, the platform 28 keeps the reagent from spreading beyond the platform 28 or the sample testing region 34. Further, when a reagent is uniformly deposited on the platform 28, a uniform thickness of reagent and a uniform reaction area

are achieved. According to some embodiments of the present invention, reagent combines with a sample within the sample testing region 34 to result in a colormetric reaction. The resulting color may be analyzed using diffuse reflectance or transmission through the sample.

According to some embodiments of the present invention, adhesive is provided between the format members to glue the first format member 12 to the second format member 14. In one embodiment of the present invention, heat-activated optically-clear adhesive is coated onto the inner surface of one or both of the format members for adhesion of the format members.

According to some embodiments of the present invention, top and bottom optical format members both comprise optically clear material. These embodiments may be used for optical transmission or diffuse reflectance analysis. Alternatively, one of the optical format members may comprise optically reflective material. Embodiments using optically reflecting material may be used in optical analysis based on diffused or reflected light from a sample.

The formats and methods of the present invention allow for the efficient construction of small and reliable optical formats. As shown in FIG. 1, a format has a format length l_f, a format width w_f, and a format height h_f. According to one embodiment of the present invention, the format length is approximately 3.85 mm, the format width is approximately 3 mm, and the format height is approximately 1 mm. Formats having other dimensions may be preferred in some embodiments of the present invention. For example, format lengths ranging from about 3.00 mm to about 12.5 mm, format widths ranging from about 2.00 mm to about 5.00 mm, and format heights ranging from about 0.50 mm to about 3.00 mm are preferred in some embodiments of the present invention. Optical formats according to the present invention may be designed for handling a wide range of sample fluid volumes. For example, sample volumes from about 5 nl to about 1000 nl are contemplated in some embodiments of the present invention. While the present invention has been described with reference to one or more particular embodiments, those skilled in the art will recognize that many changes may be made thereto without departing from the spirit and scope of the present invention.

For example, while the present invention has been generally described as directed to medical applications it is to be understood that other optical fluid testing applications

might employ the principles of the invention. Each of these embodiments and obvious variations thereof is contemplated as falling within the spirit and scope of the claimed invention, which is set forth in the following claims.